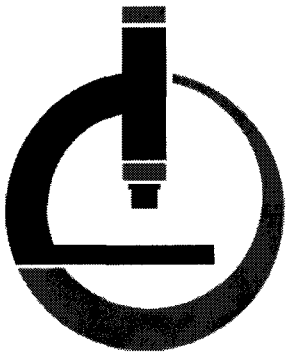
ET Doc. 13-208

"Improving Laboratories Through Accreditation"



LABORATORY ACCREDITATION BUREAU ®

L-A-B Assessor Handbook

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1.0 Introduction

1.1 Purpose

This handbook was developed for potential and current L-A-B assessors describing the assessment process. This document provides L-A-B procedures for selecting, training, approving and monitoring the performance of assessors and technical experts.

1.2 History

L-A-B is a Limited Liability Company, incorporated in the state of Michigan. L-A-B is organized in a manner to assure that all personnel involved in the accreditation process have the necessary education, training, technical knowledge and experience for handling the type, range and volume of work performed.

1.3 Quality Policy

Laboratory Accreditation Bureau attests to the competence of laboratories. L-A-B facilitates trade by promoting global acceptance of accredited laboratories. The confidence of L-A-B's accreditation originates in our mutual recognition and peer evaluation. L-A-B provides all accredited laboratories confidence in accreditation and the ability to accept test reports and calibration certificates nationally and internationally. Service, communication and integrity back the attestation and the ability to gain confidence in L-A-B's Accreditation Programs.

1.4 L-A-B Objectives

Laboratory Accreditation Bureau is a recognized accreditation body, dedicating itself to continually providing service for our client's needs, improving the quality of laboratories and the services they provide, increasing the acceptance of accredited laboratories worldwide, complying with ISO/IEC 17011.

1.5 Who We Are

Laboratory Accreditation Bureau, a Michigan corporation, was established to provide laboratory accreditation services to independent and captive, testing and calibration laboratories across North America and the world. Laboratory Accreditation Bureau is internationally recognized and conforms to ISO/IEC 17011 in assessing and accrediting laboratories to ISO/IEC 17025.

1.6 Why L-A-B

The founding of L-A-B was based on a single uncompromising goal to provide testing and calibration laboratories with superior accreditation services, performed by a team of qualified assessors. Timely response is a top priority. L-A-B realizes that many laboratories are subject to time-sensitive mandates and strives to schedule and conduct assessments to client timetables. The goal is to process reports and issue certificates with minimal delay.

Assessor selection criteria include experience, overall qualifications, communication/interpersonal capabilities and geographic representation - to provide the best combination of functional and relational skills.

Global harmonization of national and industry-specific standards is accelerating. This means that, in the future, suppliers will contend with compliance to fewer, more consistent, and more widely recognized standards. These requirements will extend deeper into the supply chain, impacting companies that previously were excluded from having to meet formal requirements.

1.7 Authority and Recognition

Laboratory Accreditation Bureau is a signatory to the Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement (MRA) effective December 6, 2007. L-A-B is a full member of the International Laboratory Accreditation Cooperation (ILAC) whereby L-A-B will recognize, and be fully recognized by, ILAC signatories worldwide.

L-A-B has achieved full national recognition through NACLA (National Cooperation for Laboratory Accreditation) for testing and calibration. Additionally, L-A-B is recognized nationally by Regulators and Specifiers (Automotive, Aerospace, Industrial, Manufacturing, Medical, Military, Government Agencies) for program specific requirements.

The USA automotive industry has provided acceptance of L-A-B as an accreditation body suitable for the purpose of demonstrating conformance of laboratories to the requirements for laboratories within the QS-9000 standard.

Further authority of L-A-B is by virtue of the acceptance by others of L-A-B accredited laboratories and the data and services they provide.

1.8 Fields of Recognition

L-A-B is recognized to provide ISO / IEC 17025 accreditation services in all fields of testing and calibration.

1.9 References

L-A-B Quality Manual
ISO/IEC 17011 – General Requirements for Accreditation Bodies
ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories

1.10 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/24/09	Jason Stine	

2.0 Role and Responsibilities

2.1 L-A-B Role and Responsibility

Laboratory Accreditation Bureau attests to the competence of laboratories. L-A-B facilitates trade by promoting global acceptance of accredited laboratories. The confidence of L-A-B's accreditation originates in our mutual recognition and peer evaluation. L-A-B provides all accredited laboratories confidence in accreditation and the ability to accept test reports and calibration certificates nationally and internationally. Service, communication and integrity back the attestation and the ability to gain confidence in L-A-B's Accreditation Programs.

2.2 Client Role and Responsibility

The responsibilities of the Laboratory include but are not limited to the following:

a) To receive the assessment team and provide them with the necessary cooperation and facilities to perform the assessment;

b) To allow the assessment team access to all laboratory facilities, personnel, and records necessary for the purposes of confirming the laboratory's compliance with the requirements of accreditation for the proposed Scope of Accreditation;

c) To supply any information needed for the evaluation of the laboratory;

d) Comply with the relevant provisions of the accreditation requirements.

e) Claim accreditation only for those test(s) / calibration(s) represented on the approved Scope of Accreditation.

f) Not use its accreditation in such a way to bring L-A-B into disrepute nor make statements relevant to its accredited status that may be misleading;

g) Upon suspension or withdrawal of accreditation, discontinue use of all advertising that contains reference to L-A-B and return certificates of accreditation to L-A-B;

h) Not use its accreditation to imply product approval by L-A-B;

i) Ensure that marketing material, certificates, or reports or parts thereof are not used in a misleading manner;

j) Permit L-A-B to disclose and publish its name as a L-A-B client;

k) Not hold liable L-A-B, or its representatives, for any damages or loss resulting from, or in any way connected with, the services provided by L-A-B to the applicant, except in such damage or loss arising from gross negligence by L-A-B.

2.3 Assessor Role and Responsibility

Assessors and Technical Experts play a vital role for the Accreditation Body. The effectiveness and credibility of an accreditation body depends on the competence, professionalism and integrity of its Assessors and Technical Experts. In order to be accepted and recognized internationally, an accreditation system must comply with the requirements of ISO/IEC 17011, including the need to have an effective system for ensuring the competence of its Assessors and Technical Experts by establishing, implementing and maintaining procedures for qualifying and monitoring the performance and competence of the personnel involved.

Assessors must have direct laboratory experience in the fields of testing and calibration for which they will be performing assessments. They are trained in the use of the methods and documents used for assessments. L-A-B has an extensive training program that verifies an Assessor's technical qualification. Assessors must be able to communicate effectively both orally and in writing while maintaining a suitable and effective personality. Assessors will have relevant knowledge of different assessment methods and of legal regulations in their field of expertise. Records of Assessor's qualifications and training are kept on file.

Assessors are required to understand, and are provided with all policies and procedures necessary to perform assessments for L-A-B. Assessors are notified by e-mail when new or revised documents that directly affect their responsibilities are published.

2.4 Technical Advisory Group (TAG) Role and Responsibility

L-A-B has established a Technical Advisory Group (TAG) which is made up of Technical Experts in the fields of Testing, Calibration, and Dimensional Inspection. TAG members consist of professionals representing various industries such as Regulators, Specifiers, Laboratories, and PT / ILC Providers. The TAG helps to improve the overall quality of services provided by L-A-B through participating in the development of policies and procedures relating to the technical aspects of the accreditation process.

Participation in the Technical Advisory Group is voluntary and membership is open to anybody with the appropriate qualifications. Applications are available on the L-A-B website or upon request.

Mission of the TAG:

Competence

- We have the experience and expertise to assess and accredit laboratories.
- We assure compliance to the standard and technical competence of the laboratory to the scope.

Confidence

- We foster confidence in what we do by the result that the laboratory produces and what we support in that production (scopes).

Communication

- We keep an open line to all seeking knowledge in improvement.

Consistency

- We promote consistent accreditation by following what is written and writing what is needed.

The TAG currently consists of an executive level and various committees which are designed to focus on specific areas of accreditation. Members of the executive TAG are made up of the chairs and vice chairs of the various committees and are responsible for each of these committees. Each charter has specific goals and objectives and has established working groups as needed to address specific technical fields.

2.5 References

ISO/IEC 17011 – General Requirements for Accreditation Bodies
L-A-B Quality Manual
L-A-B Form R20.30 – Independent Contractor Agreement
L-A-B Form R20.40 – L-A-B Client Agreement
L-A-B Client Instruction Manual
TAG Application
TAG Charters

2.6 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/24/09	Jason Stine	

3.0 Code of Ethics

3.1 Impartiality

Laboratory Accreditation Bureau is organized, structured, and operated so as to safeguard the objectivity and impartiality of its activities. Conformity assessment services and consultancy cannot be provided by L-A-B or its employees in order to uphold impartiality. Each decision on accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment. L-A-B ensures that the activities of its related bodies do not compromise the confidentiality, objectivity and impartiality of its accreditations.

3.2 Ethics and Code of Conduct

All L-A-B contract, leased, temporary, permanent staff, technical experts, assessors or instructors, are required to sign the appropriate L-A-B Ethics and Code of Conduct forms to confirm formally their willingness to observe and be bound by the following code:

a) To act in a strictly trustworthy and unbiased manner in relation to both L-A-B and any organizations involved in an assessment by them or personnel for whom they are responsible.

b) To disclose to L-A-B any relationships they may have with the organization to be assessed before undertaking any assessment function concerning said organization.

c) Not to accept any inducement, gift, commission, discount or any other profit from the organizations assessed, from their representatives, or from any other interested person nor knowingly allow personnel from whom they are responsible to do so.

d) To maintain confidentiality; not to disclose the findings, or any part of them, or the assessment team responsible, or any other information gained in the course of an assessment process to any third party, unless authorized in writing by both the assessed organization and the Executive Director of L-A-B.

e) Not to act in any way prejudicial to the reputation or interests of L-A-B, or to the assessed organization.

f) To maintain as confidential, all contract monetary information concerning L-A-B that has not otherwise been made public by L-A-B.

g) In the event of any alleged breach of this code, to cooperate fully in any formal inquiry procedure.

3.3 Conflict of Interest

As an accreditation body, L-A-B ensures that its activities do not compromise the confidentiality, objectivity and impartiality of its accreditations. Assessors and Technical Experts also must ensure the impartiality of their conduct by declaring a conflict of interest with any activity related to the laboratory and the accreditation process. The process includes but is not limited to document review, pre-assessment, initial / reassessment and technical review. As part of the technical review, TAG members must also declare a conflict with a laboratory when discovered. Assessors and Technical Experts must sign off on no conflict prior to accepting an assignment.

As a result:

a) All Assessors and Technical Experts must disclose to L-A-B any professional, financial, and work related interest that could be construed as a potential conflict of interest;

b) All Assessors and Technical Experts agree to hold in confidence all information received from each laboratory and L-A-B unless the law requires such information disclosed without L-A-B's consent;

c) All Assessors shall sign this Assessor Handbook declaring that they understand and agree with all content which ensures that they are not subject to any undue influences or pressure that might affect their integrity;

d) All Assessors and Technical Experts should act objectively and must be free from any undue any commercial, financial or other pressures which could compromise impartiality;

e) All Assessors and Technical Experts shall not consult with laboratories that they have assessed at least until the time of the responsibilities for the issues of that particular laboratory have been fully discharged. L-A-B staff shall not consult with laboratories. Assessors and Technical Experts contracted to review technical packages shall disclose immediately if they or their affiliates have consulted directly with any laboratory that may give the appearance of a conflict of interest and shall not make any decision related to that laboratory;

f) All Assessors and Technical Experts maintain as confidential, all contract monetary information concerning L-A-B that has not otherwise been made public by L-A-B;

g) In the event of any alleged breach of this code, to cooperate fully in any formal inquiry procedure.

3.4 Consultancy

All Assessors or Technical Experts must not have offered any type of consultancy to the laboratories for which they are assigned in the past two years. All Assessors and Technical Experts must sign off on no conflict prior to accepting an assignment.

3.5 Additional Agreements

Assessors must agree to and sign the L-A-B Form R20.40 - Secrecy and Non-Solicitation Agreement and L-A-B Form R20.30 – Independent Contractor Agreement prior to any assignments. L-A-B specific programs may have additional requirements.

3.6 References

L-A-B Form R20.10 – Ethics and Code of Conduct

L-A-B Form R20.29 – Conflict of Interest

L-A-B Form R20.30 – Independent Contractor Agreement

L-A-B Form R20.40 - Secrecy and Non-Solicitation Agreement

3.7 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/24/09	Jason Stine	

4.0 Assessor and Technical Expert Qualifications

4.1 Purpose

This document defines the qualification criteria, Assessor attributes, and specific L-A-B Assessor job functions utilized during the assessment process.

4.2 Responsibility

The L-A-B Managing Director is responsible to assure that only qualified Assessors and Technical Experts are utilized by L-A-B.

4.3 Initial Qualification

4.3.1 Working (Technical) Experience

All L-A-B Assessors are required to have at least four years of laboratory technical experience in a specific technical field of testing or calibration is. Experience in quality management, quality assurance or quality system auditing related to laboratory and/or inspection activities is preferred. Assessor assignments are based on the specific areas of technical competence. L-A-B specific programs may have additional qualification requirements.

4.3.2 Training

Successful completion of a training course or a combination of training courses which covers ISO/IEC 17025 accreditation criteria. Proof of successful completion is required prior to assignment on an assessment team. L-A-B specific programs may have additional qualification requirements.

Note - Training on L-A-B policies, procedures and the forms necessary to perform an assessment will be provided by L-A-B to potential Assessors that have met the initial qualification requirements.

4.3.3 Assessment Experience

ISO/IEC 17025 or equivalent quality system and assessment experience as determined by L-A-B.

4.3.4 Required Documentation

Prospective Assessors are to submit the following L-A-B forms detailing their qualifications:

a) Current resume including education, work history and technical background;
b) Professional references that can attest to work performance;
c) Prior work examples such as Assessor reports, assessment plans, or other writing samples;
d) L-A-B Form 41 - Assessor Qualifications Survey;
e) L-A-B Form 209.4 - Assessor Major Field and Discipline Self Rating.

4.3.5 Interview and Competence Assessment

L-A-B Program Managers and technical staff will use all of the information provided, collected, and obtained through the interview process to determine if the initial qualifications are met.

From this information, L-A-B will determine what specific fields of testing or calibration the Assessor may qualify to assess and whether the Assessor has the appropriate technical competence required by L-A-B.

During this initial qualification, potential Assessors must; review, understand, and sign the L-A-B Ethics and Code of Conduct, Conflict of Interest, R20.30 -Independent Contractor Agreement, and R20.40 - Secrecy and Non-Solicitation Agreement.

4.4 Assessor Attributes

Assessors need to be competent in order to effectively plan and conduct assessments and report assessment results. An Assessor's competence is based on the foundation provided by education, training and experience. Assessor competence is measured by the demonstration of the application of specific Assessor knowledge, skills and personal attributes,

4.4.1 Assessors Should:

a) Be open minded and mature and willing to consider alternative ideas or points of view;
b) Possess sound judgment, analytical skills, and tenacity;
c) Have the ability to perceive situations in a realistic way to understand complex operations from a broad perspective and to understand the role of individual units within an organization;
d) Be able to distinguish crucial or essential points from less important ones;
e) Be ethical – fair, truthful, sincere, honest and discreet;
f) Be diplomatic – tactful in dealing with people;
g) Be observant – actively aware of physical surroundings and activities and habits;
h) Be tenacious – persistent, focused on achieving objectives;
i) Be decisive – reach timely conclusions based on logical reasoning and analysis;
j) Be self-reliant – act and function independently while interacting effectively with others.

4.4.2 Assessors Should Be Able To Apply The Attributes Listed Above In Order To:

a) Obtain and assess objective evidence fairly;
b) Remain true to the purpose of the assessment without fear or favor;
c) Evaluate constantly the effects of assessment observations and personal interactions during an assessment;
d) Treat concerned personnel in a way that will best achieve the assessment objective;
e) React with sensitivity to the national conventions of the country in which the assessment is performed;
f) Perform the assessment process without deviating due to distractions;
g) Commit full attention and support to the assessment process;
h) React effectively in stressful situations;

i) Arrive at generally acceptable conclusions based on objective evidence collected during assessments;

j) Remain true to a conclusion despite pressure to change that is not based on objective evidence.

4.5 Assessor Knowledge and Skills

4.5.1 Knowledge and Skills in Applying Accreditation Criteria

Assessors shall understand all L-A-B policies, procedures, ISO/IEC 17025 and if necessary, the applicable L-A-B program specific requirement documents.

Assessors should also appropriately interpret and apply the criteria to actual assessment situations.

Assessors should demonstrate an awareness and understanding of accreditation criteria and appropriate reference documents, and the application of these requirements to assessment situations relevant to their assigned assessment functions.

4.5.2 Knowledge and Skills in Applying Assessment and Quality Principles, Practices and Techniques

Assessors should possess the knowledge and skills to apply assessment principles, practices and techniques to actual assessment situations and apply them to different assessments and still ensure that the assessments are conducted in a consistent and systematic manner. This knowledge and these skills include all the steps in the assessment process including planning, preparing, performing, reporting, following up on issues, verifying closure of non compliances from previous assessments, and closing the assessment.

Assessors should be skilled in assessment performance techniques including interviewing, audit tracing or trailing, managing time, listening, audit sampling, communicating orally and in writing, collecting assessment evidence, and analyzing assessment observations and drawing appropriate conclusions while maintaining the confidentiality and security of assessment information.

Assessors should have a general knowledge of quality systems and processes typical of the type of laboratory to be assessed. This may include, but not be limited to: historical data, quality policy and objectives, quality planning, test and/or calibration method and/or inspection procedure design, validation and implementation, quality control, quality assurance, corrective and preventive actions, and implementation of continuous improvement.

Assessors should be able to comprehend the organizational size, structure, functions and relationships of the body under assessment; its general business processes and related terminology; and the cultural and social customs of the personnel.

4.6 Lead Assessor Knowledge and Responsibilities

Lead Assessors are technically competent individuals who have been trained by L-A-B and reviewed by his peers. Lead Assessors must have all of the attributes, knowledge, and skills detailed above. Lead Assessors must also demonstrate additional knowledge and perform the following responsibilities. Lead Assessors are fully responsible for the performance and completion of an assigned assessment.

4.6.1 Knowledge

a) Understanding and interpretation of uncertainty of measurement;
b) Competence in analysis of proficiency testing results including interpretation of the assigned value and acceptability criteria in all relevant types of proficiency testing, including inter / intra laboratory comparisons and measurement audits, in order to afford a critical evaluation of quantitative and qualitative results of laboratories;
c) Relevant knowledge about standards and guidelines on organization, performance and evaluation of inter / intra laboratory comparisons;
d) Use of different types of proficiency testing for accreditation purposes appropriate to the work of the laboratory being assessed and in basic principles for proficiency testing;
e) Test, calibration and inspection requirements and the technical basis for those requirements;
f) Typical problem areas associated with the tests, calibrations and inspections;
g) Specific external requirements relating to the Scope of Accreditation (e.g., regulations, codes and standards);
h) Laboratory terminology associated with those tests, calibrations, inspections and related processes;
i) Knowledge of assessment techniques including techniques used for assessing professional judgment.

4.6.2 Responsibilities

a) Representing L-A-B and the assessment team with the management of the laboratory;
b) Leading the assessment team where necessary;
c) Leading the assessment team to reach conclusions;
d) Making decisions relating to the assessment;
e) Identify compliance to L-A-B requirements;
f) Identify compliance to the requirements of ISO/IEC 17025;
g) Identify compliance to all relevant additional requirements;
h) Evaluate the adequacy and effectiveness of fulfilling these requirements, when appropriate;
i) Assure proper performance of the relevant testing and calibration methods and inspection activities;
j) Relate any non-conformities found to the corresponding accreditation requirements;
k) Assisting in the selection of team members, if relevant and applicable;
l) Preparing the assessment plan and making effective use of resources during the assessment;
m) Providing direction and guidance to Assessors-in-training and Technical Experts;
n) Preventing and resolving conflicts;
o) Drafting, coordinating and submitting the assessment report in such a way that it allows the accreditation body and the assessed organization to take actions and make decisions;
p) Provide recommendations and evaluations for Team and Training Assessors;
q) Participate in the L-A-B Technical Advisory Group (TAG).

4.7 Team Assessor Knowledge and Responsibilities

A Team Assessor is a technically competent individual who has met the requirements of a Training Assessor and has been witnessed by qualified individuals selected by L-A-B. A Team Assessor is believed to have all of the necessary Lead Assessor Attributes and is approved to perform on an actual assessment as a team member.

Team Assessors may also be qualified Lead Assessors acting in the role of a Team Assessor for specific assignments. Team Assessor responsibilities are determined prior to each assignment by L-A-B and the Lead Assessor.

Responsibilities may include assessment of specific areas of the quality system or specific technical areas of the scope of accreditation.

4.8 Assessor Trainee Knowledge and Responsibilities

An Assessor Trainee is a technically competent individual, who is currently in the initial stages of Lead Assessor qualification. Assessor Trainees are currently learning the requirements of L-A-B and are under evaluation to determine if all of the attributes of a Lead Assessor are present. Assessor Trainees single function during an assessment is an observer. Assessor Trainees are not responsible for any part of an actual assessment. Assessor Trainees are required to work with L-A-B and Lead Assessors to understand the requirements of L-A-B and the functioning of an assessment.

4.9 Technical Expert Knowledge and Responsibilities

4.9.1 Knowledge

Technical Experts are assigned by L-A-B to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed. Technical Experts should demonstrate the ***Assessor Attributes*** detailed in section 4.4. The following applies:

a) Is a technically competent individual who has not been trained as an Assessor by L-A-B, but whose technical competence has been verified either by witness, peer recommendation, or reputation in their field;

b) Works under the guidance of a Lead Assessor, and can only be utilized to help evaluate technical competence of specific tests / calibrations;

c) Will always act on an assessment team with a Lead Assessor;

d) Provide technical advice but is not considered as an Assessor;

e) Should understand the fundamental basics of ISO/IEC 17025, L-A-B's policies and where necessary L-A-B program specific requirements.

4.9.2 Responsibilities

a) Work with L-A-B and the Lead Assessor to develop an assessment plan;

b) Work under the direction of the Lead Assessor to complete the assignment;

c) Utilize their technical knowledge to assure proper performance of the relevant technical activities as assigned by the Lead Assessor;

d) Provide the Lead Assessor a thorough description of any technical deficiencies identified;

e) Work with the Lead Assessor to provide any necessary documentation to support the assessment activities.

4.10 References

ISO/IEC 17011 – *General Requirements for Accreditation Bodies*
ISO/IEC 17025 – *General Requirements for the Competence of Testing and Calibration Laboratories*
ILAC-G11:07/2006 - *Guidelines on Qualifications and Competence of Assessors and Technical Experts*
L-A-B Form 41 - *Assessor Qualifications Survey*
L-A-B Form 209.4 - *Assessor Major Field and Discipline Self Rating*
L-A-B Form R20.30 – *Independent Contractor Agreement*
L-A-B Form R20.40 – *L-A-B Client Agreement*

4.11 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/24/09	Jason Stine	

5.0 Initial Training and Continued Competence

5.1 Purpose

This document defines the initial training, and continued competence requirements for Assessors and Technical Experts.

5.2 Responsibility

The L-A-B Managing Director is responsible to assure that only qualified Assessors and Technical Experts are utilized by L-A-B.

5.3 Initial Training

L-A-B will provide training to new assessors during this basic qualification period on L-A-B policies, procedures and the forms necessary to perform an assessment.

Upon completion of the basic qualification process, potential assessors will begin the initial training steps as follows:

5.3.1 Assessor Trainee

a) Assessor Trainees are responsible for providing the following information to L-A-B. All information must be complete and provided to L-A-B prior to an initial assignment:

   i. A resumé including current contact information, education, work history and technical background;

   ii. Evidence of relevant work experience detailed on L-A-B Form 41, with references who will verify the stated experiences;

   iii. A self attestation of technical competence aligned with our Major Field and Disciplines as defined on L-A-B Form 209.4. A demonstration of competence will be verified as necessary;

   iv. Brief bio completed on L-A-B Form 40 detailing experience that can be used by L-A-B to introduce the assessor to laboratories they will be assessing;

   v. Form R20.29 - Conflict of Interest Policy;

   vi. Form R20.10 - Code of Conduct;

   vii. Form R20.30 – Independent Contractor Agreement;

   viii. Form R20.40 - Secrecy and Non-Solicitation Agreement;

   ix. Additional documents as required by L-A-B specific programs.

b) Assessor Trainees will witness ***three assessments*** with a Lead Assessor before qualifying for Team Assessor status. Credit may be given for assessors qualified by other competent Accreditation Bodies or for additional circumstances as determined by L-A-B.

c) The Assessor Trainee must complete a report for each witnessed assessment. This report must contain:

i. Summary of the assessment activities;

ii. Details of the technical aspects of the assessment including an analysis of measurement uncertainty and/or fields of testing;

iii. Proof of understanding of the assessment activities and L-A-B Policies.

d) Requirements for Promotion to a Team Assessor.

a) A positive written recommendation from each Lead Assessor observed;

b) L-A-B will review the reports with the Assessor Trainee to see if further training is required prior to moving them to active status as a Team Assessor;

c) Assessor Trainees should review the L-A-B Form 209.2 - Assessor Technical Publications Library;

d) A written or oral examination may be used to determine the Assessor Trainees knowledge and skills as appropriate to determine promotion to the next level.

e) L-A-B specific programs may have additional qualification requirements.

5.3.2 Team Assessor

Once an Assessor Trainee has met the above requirements and been approved as a Team Assessor, they must complete a minimum of ***two assessments*** as part of an assessment team led by a Lead Assessor prior to achieving Lead Assessor status. The performance of the potential Assessor on these team assignments will be evaluated by the Lead Assessor or appropriate L-A-B technical staff. The Lead Assessor will generate a report on the L-A-B Assessor Evaluation Checklist. L-A-B specific programs may have additional qualification requirements.

5.3.3 Lead Assessor

Upon completion of two assessments as a team member the Team Assessor may be considered for Lead Assessor status. L-A-B will utilize interviews, evaluation reports, and other information to determine if the assessor has all attributes, knowledge, and skills necessary to be a Lead Assessor. If necessary, additional training or team assessments may be required prior to assignment as a Lead Assessor. For initial approval and assignment as a Lead Assessor a peer evaluation must be performed and documented on the appropriate L-A-B form and approved by the evaluator and L-A-B Program Managers. L-A-B specific programs may have additional qualification requirements.

5.4 Continuation Requirements

5.4.1 Regular Participation in Training Activities

a) Assessors are expected to regularly participate in L-A-B technical discussions through the TAG about policy and accreditation.

b) Assessors are also expected to participate in ongoing refresher training sessions and periodic short courses to help stay updated on evolving procedures and requirements such as:

i. NCSLI, ASTM, ASQ, ASM, ASME, SAE, NIST, IEEE, Ect...

c) Assessors are expected to attend the annual Assessor Conference which facilitates accreditation discussions;

d) Expected to update their training files with relevant certificates as proof of training;

e) Participation in professional societies, conferences, and standards writing bodies;

f) Participation as a tutor or instructor in a formal course related to assessment practice helps to develop further knowledge;

g) Overseeing and evaluating others perform assessments often provides useful insights for improving assessment practice;

h) L-A-B specific programs may have additional qualification requirements.

5.4.2 Peer Review

To maintain Lead Assessor status, a review of assessor performance which may include a review of assessment reports, feedback from the laboratories, or an onsite evaluation is required every year. An onsite peer review is required at least once every 3 years by another Lead Assessor determined by L-A-B. This review may be performed during a team assessment or during a specifically scheduled observation. Assessors may be required to participate in additional training should the review warrant. L-A-B specific programs may have additional qualification requirements.

5.5 References

ISO/IEC 17011 – *General Requirements for Accreditation Bodies*

ISO/IEC 17025 – *General Requirements for the Competence of Testing and Calibration Laboratories*

ILAC-G11:07/2006 - *Guidelines on Qualifications and Competence of Assessors and Technical Experts*

L-A-B Form 209.2 - *Assessor Technical Publications Library*

L-A-B Form 209.4 - *Assessor Major Field and Discipline Self Rating*

L-A-B Form R20.10 - *Code of Conduct*

L-A-B Form R20.29 - *Conflict of Interest Policy*

L-A-B Form R20.30 – *Independent Contractor Agreement*

L-A-B Form R20.40 – *L-A-B Client Agreement*

L-A-B Form 40 – *Assessor Bio*

L-A-B Form 41 – *Assessor Qualification*

5.6 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/24/09	Jason Stine	
Revision 1	10/05/10	Ryan Fischer	Revised the peer evaluation timeframe to 3 years

6.0 Assessment Process

6.1 Purpose

This procedure defines the process used to prepare and conduct a laboratory assessment. This procedure applies to L-A-B, the Lead Assessor, and members of the Assessment Team.

6.2 Responsibility

L-A-B staff, Lead Assessor, and members of the Assessment Team are responsible for ensuring that all functions of the assessment process are fulfilled.

6.3 Assessor Allocation

For each assessment, L-A-B utilizes only qualified Assessors and Technical Experts for a comprehensive technical evaluation of the laboratories Scope of Accreditation. Lead Assessors, Team Assessors, and Technical Experts are assigned based on individual technical competence.

L-A-B initiates the assessment process by notifying the Assessment Team Members through an Assessment Allocation. An Assessment Allocation is a formal request from L-A-B to perform a particular assignment. Allocations will include the following information:

a) Name of client laboratory to assess;
b) L-A-B accreditation programs to assess;
c) Assessor role such as Lead Assessor or Team Assessor;
d) Number of mandays assigned for this project;
e) Details for assessment preparation and reporting;
f) Identification of potential conflicts of interest;
g) Specific time frame for which the assessment must take place;
h) Any special instructions.

To accept the assignment, Assessors must notify L-A-B within one week of their acceptance of the project. Assessors must verify no conflict exists with the laboratory by signing and returning the no conflict letter provided with the allocation. Specific visit dates must be suggested within the timeframe given by L-A-B for the assessment to take place. L-A-B will notify the allocated assessment team once the dates have been confirmed by the laboratory.

6.4 Assessment Plan

The Lead Assessor, and if necessary, Assessment Team shall conduct the assessment of the laboratory at the premises of the laboratory from which one or more key activities are performed. Where relevant, shall perform technical witnessing at other selected locations where the laboratory operates, to gather objective evidence that the laboratory is competent to perform the activities detailed on the Scope of Accreditation and conforms to the relevant standard(s) and other requirements for accreditation.

The Assessment Plan is provided to the Lead Assessor with the necessary laboratory contact and location information completed by L-A-B during the allocation process. Upon notification of the confirmed assessment dates, the Lead Assessor is required to complete and submit the Assessment Plan to L-A-B within 2 weeks.

6.4.1 Responsibility

The Lead Assessor is solely responsible for organizing and completing the Assessment Plan utilizing all information and special instructions provided by L-A-B. The Lead Assessor should collaborate with Team Assessors and Technical Experts to determine the specifics of the assessment and develop an appropriate plan.

6.4.2 Information

L-A-B will provide relevant information to the Lead Assessor in order to develop an Assessment Plan. This information will include the following:

a) Client contact information;
b) L-A-B Accreditation Programs;
c) Proposed Scope of Accreditation;
d) Type of assessment (Pre, Initial, Full Assessment, Type I, Type II);
e) Prior year's assessment package including Non-Compliances with evidence of resolution;
f) L-A-B Form 001 – Traceability Tracking;
g) L-A-B Form 218.5 / 218.6 – Accreditation Tracking;
h) Additional information as necessary or as requested.

6.4.3 Requirements

The Lead Assessor should utilize the provided information and may request additional information in order to develop an appropriate Assessment Plan. Assessment Plans should clearly describe the assessment activities and be specific for each type of assessment and each laboratory.

Assessment Plans must include the location(s) to be visited, each assessment team member's responsibilities, and special instructions provided from L-A-B.

Assessment Plans shall include the following information:

Pre Assessment

A pre assessment plan should include brief coverage of all elements of ISO/IEC17025 and/or the appropriate L-A-B program requirements. May or may not include technical witnesses. Due to the limited time allotted for Preassessments technical witnessing may not be possible.

Initial / Full Assessment

a) Coverage of all elements of ISO/IEC17025, per the L-A-B Form 205.5 - Assessment Matrix. Or coverage of all elements of the specific L-A-B program requirements;
b) Verification of effective implementation of past corrective actions;
c) Technical evaluation of the Full Scope of Accreditation meeting the requirements of L-A-B Policy 010 – Technical Competence Evaluation for Laboratories.

Type I Surveillance

a) Coverage of the appropriate elements of ISO/IEC17025, per the L-A-B Form 205.5 - Assessment Matrix. Or coverage of the appropriate elements of the specific L-A-B program requirements;
b) Verification of effective implementation of past corrective actions;
c) Technical evaluation of the Scope of Accreditation must meet the requirements of L-A-B Policy 010 – Technical Competence Evaluation for Laboratories.

Type II Surveillance

a) Coverage of the appropriate elements of ISO/IEC17025, per the L-A-B Form 205.5 - Assessment Matrix. Or coverage of the appropriate elements of the specific L-A-B program requirements;

b) Verification of effective implementation of past corrective actions;

c) Technical evaluation of the Scope of Accreditation must meet the requirements of L-A-B Policy 010 – Technical Competence Evaluation for Laboratories. Parameters that were not technically witnessed in the previous year's surveillance assessment will need to be reviewed as part of the Type II Surveillance. To accomplish the witnessing, the L-A-B Technical Staff may identify the needed parameters to be witnessed during the allocation process.

Multi-site Assessments

Assessment Plans for Multi-site assessments must clearly detail the locations to be visited and meet the requirements of L-A-B Policy 009 - Accreditation of Multiple-Site Laboratories.

6.5 Documentation Review

Laboratory quality documentation will be provided to the Lead Assessor and assessment team members for review prior to the assessment. A documentation review helps the assessment team prepare for the upcoming assessment and potentially identify and address areas of concern with the laboratories quality documentation prior to assessment day.

6.5.1 Responsibility

L-A-B is responsible to request and receive the appropriate laboratory quality documentation prior to the assessment. L-A-B will perform a cursory review to assure the appropriate documents are received and suitable to provide to the Assessment Team.

The Lead Assessor is responsible for performing and documenting a review of the laboratories assessment documentation prior to the scheduled assessment. For Team or Technical Expert assessments, L-A-B and the Lead Assessor will determine the distribution of documents for review by the assessment team. The Lead Assessor and Team Assessor, if assigned, are responsible to perform and document this review on the appropriate L-A-B document review form.

6.5.2 Requirements

The document review performed by the Lead Assessor and/or Assessment Team shall include:

a) Evaluation of the client completed L-A-B assessment checklist(s) for compliance with the requirements of ISO/IEC 17025, L-A-B requirements and/or L-A-B Program Requirements in comparison to the client supplied documents;

b) Further evaluation of the client's Scope of Accreditation and associated uncertainty budgets;

c) Review the Management Review and Internal Audits;

d) Review the PT / ILC procedure and results for satisfactory participation and the corrective action if needed;

e) Review of additional information provided by the laboratory.

The Lead Assessor or assigned Team Member shall provide document review comments and observations on the appropriate L-A-B Document Review Form. The Lead Assessor shall inform the client of any observations or requirements the laboratory may need to address prior to the assessment.

6.5.3 Preassessment Document Review Requirements

The Lead Assessor is responsible for performing and documenting a review of the laboratories preassessment documentation prior to the scheduled preassessment on the appropriate L-A-B document review form.

6.6 Assessment – Opening Meeting

The purpose of the team meeting prior to the assessment is to discuss assessment activities and any open issues from the document review. An opening meeting is utilized to assure that the Assessment Plan is adhered to and the required assessment activities are completed as planned.

6.6.1 Team Meeting

If the assessment utilizes a Team Member or Technical Expert, the assessment team shall have a meeting prior to beginning the assessment. The following should be considered at this meeting:

a) How the specific responsibilities for activities will be assigned to each Assessor or Expert. If a conflict arises during this process, the Lead Assessor shall make the final decision;
b) Techniques for accomplishing the full agenda in the allotted time;
c) Any concerns the Lead Assessor or assessment team members have that may require special attention during the assessment process;
d) Preassessment results shall be discussed, and those areas of weakness discovered shall be addressed;
e) The team should agree on the starting times, daily wrap up times, and final briefing time.

6.6.2 Opening Meeting

A formal opening meeting shall be held by the Lead Assessor at the beginning of the assessment to clearly define the purpose of the assessment and accreditation criteria. The opening meeting shall be completed as detailed in L-A-B Form 205.2 - Opening Meeting Minutes. The Assessment Plan describes the opening meeting activities and provides a record of this meeting.

The opening meeting attendees should include:

a) Assessment team;
b) Laboratory contact;
c) Laboratory management personnel responsible for quality or technical aspects of the laboratory;
d) Other company management or staff wishing to attend.

An L-A-B Form 32 - Participants List shall be circulated to obtain a record of individuals present during any part of the assessment.

Multi-site Assessments

For Multi-site Assessments, an opening meeting should be performed at the start of **each site**. A Form 32 - Participants List shall be circulated to obtain a record of individuals present during any part of the assessment.

6.7 Assessment – General Requirements

The Lead Assessor and Assessment Team shall analyze all relevant information and evidence gathered during the document and record review and the on-site assessment. This analysis shall be sufficient to allow the Lead Assessor to determine the extent of competence and conformity of the laboratory within the requirements for Accreditation. The Lead Assessor and Assessment Team's observations on areas for possible improvement may be presented to the laboratory. However, consultancy shall not be provided.

6.7.1 Initial and Full Reassessments

The Lead Assessor shall complete the appropriate Assessment Checklists and provide details of compliance for each element of the requirements such as ISO/IEC 17025 or L-A-B Program Requirements. The Lead Assessor shall indicate any areas of Non-Compliance, areas that require improvement, and where exceptionally good practices exist. It is extremely important that the assessment documentation provide enough comments on the laboratory's compliance with each requirement for L-A-B to establish an accreditation decision.

For Team Assessments, the Lead Assessor may delegate sections of the Assessment Checklists to be completed by the assessment team member. Upon completion of the assessment, this information shall be reviewed by the Lead Assessor and combined into a single Assessment Checklist to be submitted with the assessment package.

6.7.2 Surveillance Assessment

The Lead Assessor must complete the appropriate L-A-B Surveillance Checklists providing assessment details and indicating compliance of all applicable requirements such as ISO/IEC 17025 or L-A-B Program Requirements. The Lead Assessor shall indicate any areas of Non-Compliance, areas that require improvement, and where exceptionally good practices exist. It is extremely important that the assessment documentation provide enough comments on the laboratory's compliance with the applicable requirements for L-A-B to establish an accreditation decision.

For Team Assessments, the Lead Assessor may delegate sections of the surveillance checklist to be completed by the assessment team member. Upon completion of the assessment, this information shall be reviewed by the Lead Assessor and combined into a single checklist to be submitted with the assessment package.

6.7.3 Pre assessment

A pre-assessment is a brief look at the laboratory's Quality Management System to assess the laboratory's preparedness for the accreditation process. Where possible in the allotted time, the Lead Assessor may briefly examine the laboratory's technical capabilities.

The Lead Assessor shall provide a summary report of the preassessment activities, including the document review. This report may be provided to L-A-B in any format that would provide good detail and description of the preassessment activities. **The Assessor SHALL NOT provide consultancy**.

6.8 Assessment – Technical Evaluation

The L-A-B assessment team shall technically witness the performance of a representative number of staff of the laboratory to provide assurance of the technical competence of the laboratory across the scope of accreditation.

Technical evaluation of the laboratories scope of accreditation must include evaluation of the specific scope parameters and all supporting technical activities necessary for the correct performance of the scope item. This evaluation may be performed through **O**bserving the scope item being performed, **I**nterviewing the appropriate personnel responsible for assuring the correct performance of the scope item, review of **P**rocedures and supporting documentation, and inspecting the **E**quipment necessary for the correct performance of the scope item (**O,I,P,E**).

6.8.1 Responsibility

It is the responsibility of L-A-B to assure that only qualified personnel are assigned to perform the technical evaluation of the laboratories scope of accreditation and supporting technical activities. The Lead Assessor is responsible to assure that the appropriate technical evaluation is performed and documented meeting the requirements of L-A-B Policy 010 – Technical Competence Evaluation for Laboratories and L-A-B program requirements. For team assessments, the technical evaluation may be divided up between qualified team members. Lead Assessor is responsible to assure that Team Assessors and Technical Experts stay on schedule per the assessment plan and perform the necessary technical evaluation of the scope parameters.

6.8.2 Evaluation

It is the responsibility of the Lead Assessor to determine the competence of the laboratory to perform ALL of the tests / calibrations that are specified on their Scope of Accreditation and all supporting technical activities such as in-house calibrations per the requirements of L-A-B Policy 010 – Technical Competence Evaluation for Laboratories.

Technical evaluations shall include but not be limited to the following:

a) Assure the competence and authority of the personnel performing technical activities;
b) Assure the competence and authority of the personnel issuing test and calibration results;
c) Assure the accommodations and environmental conditions for correct performance of test or calibration;
d) Assure the technical competence of appropriate laboratory personnel to perform all items listed on the scope accreditation either in the lab or onsite;
e) Assure the suitability and implementation of each test / calibration method including laboratory developed methods or modifications to methods;
f) Assure the suitability of equipment for compliance with specifications and method(s);
g) Assure the equipments calibration and maintenance status, and functionality;
h) Assure the appropriate use and validity of reference standards;
i) Assure the appropriate sampling activities are performed where necessary;
j) Assure the appropriate handling and control of data;
k) Assure the appropriate handling of test and calibration items;
l) Assure the appropriate quality assurance activities performed;
m) Assure the appropriate reporting of results.

6.8.3 Scope of Accreditation

The technical evaluation of the Scope of Accreditation must include the following:

a) The validity of the Calibration and Measurement Capability shall be challenged against the laboratories uncertainty of measurement. This should include the evaluation of the method used to determine the Calibration and Measurement Capability, the uncertainty budgets, and supporting experimental evidence;

*NOTE - **Annex A** of this Assessor Handbook and L-A-B Form 230 – Uncertainty Budget Checklist provide additional guidance in assessing the CMC on the scope.*

b) Any discrepancies between the Scope of Accreditation and the Lead Assessors evaluation of the uncertainty and CMC shall be cited a Non-Compliance;

c) All modifications to the Scope of Accreditation must be clearly identified by marking directly on the laboratory's current Scope of Accreditation;

i) All major scope additions (such as the addition of a new technology) requested by the laboratory during the assessment must first obtain the approval of L-A-B. This assures that the appropriate time is allotted for the Lead Assessor or Assessment Team to complete this task.

d) All Assessment Team Members, where necessary the Technical Experts and laboratory technical representative shall **sign** the agreed-upon Scope of Accreditation for inclusion in the technical package submittal to L-A-B (see the section 8.0 for additional details).

6.8.4 Documentation of Technical Activities

While the Assessment Checklists allow for commenting on the clients quality system, it does not provide adequate evidence for the technical evaluation of the laboratory's ability to perform the specific tests or calibrations on the proposed Scope of Accreditation. The Lead Assessor and Assessment Team are responsible for sufficiently documenting their technical activities performed during the assessment to provide L-A-B enough information to establish an accreditation decision on the technical competence of the laboratory.

6.8.4.1 Technical Competence Evaluation Checklist

a) L-A-B utilizes the L-A-B Form 205.1 – Technical Competency Evaluation as the primary form for documenting the technical activities performed during the assessment;

b) L-A-B programs may also utilize specific Technical Competence Evaluation Checklists designed to identify key elements of the technical evaluation to be documented;

c) The Lead Assessor or Team Assessor, as assigned by the Lead, is responsible for completing the appropriate checklist for each location visited;

d) The laboratory is responsible for providing the samples for the tests / calibrations that are on their proposed scope;

e) Technically competent assessment team members must witness **ALL** test / calibration that the laboratory wishes to have on their Scope of Accreditation;

f) The technical competence evaluation checklists, highlights the important factors from ISO/IEC 17025 and L-A-B Programs that should be verified for each test / calibration. The Technical Assessor is responsible for verifying the specific test / calibration to assure that the laboratory is performing correctly;

g) For on-site witnessing, the column shall be marked appropriately with the location and relevant information in the notes;

h) For in-house calibrations, the column shall be marked appropriately to indicate that the laboratory meets the requirements of L-A-B Policy 010 - Technical Competence Evaluation for Laboratories.

6.8.4.2 L-A-B Form 001 - Traceability Tracking

a) All laboratories are required to complete the L-A-B Form 001 – Traceability Tracking for each accredited location;

b) This form is required to be kept up to date by the laboratory and provided to L-A-B for review and distribution to the Lead Assessor prior to the assessment;

c) L-A-B utilizes this form to identify all in house calibrations and provide a snapshot of traceability;

d) The Lead Assessor shall utilize this form as a tool to assist in the assessment process;

e) The Lead Assessor shall verify the information provided on this form and modify if required to assure appropriate documentation of the laboratories in house calibrations and traceability;

f) Assessors are required to issue a non-compliance if the laboratory does not have this document completed or up to date. *Note – Assessors may assist the laboratory in completing this document during the assessment.*

6.8.4.3 Technical Expert Activities

A Technical Expert is utilized to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed. Tech Experts are considered an assessment team member who provides technical advice but is not considered as an Assessor unless he/she has the relevant Assessor qualifications and training.

Technical Experts without a basic understanding of the standard being assessed (ISO/IEC 17025, or specific L-A-B Program Requirements) and L-A-B's policies and procedures, must always be escorted by a qualified assessment Team Member. ("Escorted" means close supervision throughout the assessment activity.)

The Lead Assessor is fully responsible for determining the laboratories compliance with relevant specifications and accreditation criteria utilizing the input from the Technical Expert. Technical Experts may vary in their knowledge of ISO/IEC 17025 and accreditation requirements. It is up to the Lead Assessor to determine the extent of the supervision that the Technical Expert will require.

Technical Experts are required to compile a summary of their assessment activities which include the following:

a) Detailed list of the scope parameters technically witnessed;

b) List of laboratory personnel observed;

c) Comments on competence of personnel;

d) Comments on the suitability of equipment;

e) Comments on the validity of laboratory developed procedures;

f) Comments on the PT activities available / performed.

Technical Experts are required to provide their assessment summary notes to the Lead Assessor for inclusion in the assessment report. Technical Experts may utilize the L-A-B Form 205.1 – Technical Competence Evaluation to document their activities. Technical Expert notes and comments are to be provided to L-A-B upon submission of the L-A-B expense report. Detailed notes are essential for L-A-B to help establish an accreditation decision.

6.9 Non-Compliance

One aspect of the assessment is to ensure that the laboratories management system is in compliance with ISO/IEC 17025 and L-A-B general and program specific requirements. Laboratory staff members must also demonstrate an understanding and following of their procedures. However, the key aspect of the assessment is the determination of competence of staff and the technical validity of the operations. This assessment process requires the professional judgment of the Assessors and Experts. Where it is considered that key technical managers or other key staff is not competent or where the technical validity of the testing or calibration work does not meet requirements, a Non-Compliance with one or more elements of ISO/IEC 17025 or the appropriate program requirements will need to be raised.

The nature of Non-Compliances may include but not limited to the following:

a) Documentation not conforming with the requirements of the standard;
b) Staff are not following documented procedure;
c) Technical Managers or other key staff not demonstrating competence in the work they are doing;
d) Operational procedures such as test or measurement methods, traceability, etc., lacking technical validity;
e) A breakdown in the operation of the quality management system of the laboratory;
f) The laboratory not conforming to the requirements of L-A-B.

Because accreditation is primarily concerned with providing assurance to the customers of laboratories that their staff are competent and their procedures and results are technically valid, then Non-Compliances related to technical activities would normally be viewed as more serious than Non-Compliances related to the management requirements where the validity of results may not be in question (note that some elements in section 4 of ISO/IEC 17025 are technical elements). However, management requirement Non-Compliances that jeopardize the whole quality system of the laboratory would also need to be regarded as more serious.

6.9.1 Responsibility

The Lead Assessor is fully responsible for issuing Non-Compliances during an assessment. For team assessments, Team Members and Technical Experts must present potential Non-Compliances or concerns to the Lead Assessor for the final determination of Non-Compliance.

6.9.2 Issuing Non-Compliances

The Lead Assessor should discuss any negative findings or Non-Compliances with the client representative at the time they are discovered. The Lead Assessor should allow, and provide the laboratory sufficient time to discuss any concerns or questions they may have prior to the closing meeting.

The Lead Assessor must issue Non-Compliances against specific elements of ISO/IEC17025, L-A-B general or specific program requirements, or the laboratories own quality system requirements. Non-Compliances shall be documented on L-A-B Form 33 – Non-Compliance Report. Documentation of Non-Compliances must provide sufficient detail and should include specific reference to observations and evidence supporting the Non-Compliance.

***NOTE** - See Section 8 for additional details on how to complete the Form 33 – Non-Compliance Report.*

6.9.3 Serious Non-Compliances

The Lead Assessor, with input from the assessment team, may decide Non-Compliances are serious. The seriousness of the situation is left up to the Lead Assessor. For serious Non-Compliances the Lead Assessor may **recommend**:

a) Immediate suspension;
b) Removal of scope items;
c) Follow up visit;
d) Desk review of documentation.

Non-Compliances that are determined by the Lead Assessor to be a serious issue shall be indicated on the Form 33 – Non-Compliance Report and the Form 14 – Assessment Report in the appropriate location. These are considered recommendations until discussed with L-A-B and agreed upon. Non-Compliances that are not considered serious are typically verified during the next assessment.

***NOTE** - The Lead Assessor may at any time call L-A-B and discuss the situation with the appropriate Program Manager or Managing Director to help establish the seriousness of an issue.*

6.9.4 – Objective Evidence

The assessment team may collect objective evidence to support any non-compliances issued to the laboratory. This evidence may be useful to support the non-compliance and help answer questions in case of an appeal. This is not required, but is encouraged.

6.9.5 – Appeal Process

If an agreement with the laboratory cannot be reached on any decision during the assessment, the laboratory may utilize the L-A-B appeals process (SOP 203 – Appeals, Complaints, and Disputes). The Lead Assessor should make every effort to resolve any disagreements during the assessment but for time management may agree to disagree and refer to the L-A-B appeals process. This SOP is available to the laboratory and may be utilized when necessary.

***NOTE** - The Lead Assessor and laboratory representative may at any time call L-A-B and discuss the situation with the appropriate Program Manager or Managing Director to help resolve without utilizing the appeals process.*

6.10 Daily Debriefing

Each day prior to leaving the client's facility, the assessment team shall conduct a meeting with laboratory representatives. The team shall discuss any concerns or Non-Compliances for this day, and allow the client time to present any information that may be necessary to clarify findings made during the assessment activities. The client should not be surprised on the last assessment day by previously undisclosed negative findings presented during the closing meeting.

6.11 Final Team Meeting

On the final day of the assessment, the Assessment Team shall meet prior to the closing meeting to discuss their assessment findings. The Lead Assessor, with input from the Assessment Team shall prepare a summary of assessment activities and document all Non-Compliances. Notes taken during the assessment process are critical to making a decision about granting accreditation. The assessment team should take good notes to help prepare the summary report for the client and L-A-B. These notes should be detailed on the appropriate Assessment Checklists.

6.12 Closing Meeting

For completion of the assessment, the Lead Assessor, Assessment Team, and laboratory representatives shall meet to discuss the outcome of the assessment. The Lead Assessor shall complete the L-A-B Form 14 – Assessment Report and present this document during the closing meeting with laboratory representatives. The Lead Assessor shall specifically address the topics identified on the Form 14 and discuss in detail any Non-Compliances issued to the laboratory. The laboratory shall have an opportunity to ask questions and clarify any factual mistakes. The Lead Assessor shall review the L-A-B documentation with the laboratory and leave the required copies for the laboratory (L-A-B required documentation detailed in section 8.0).

6.13 References

ISO/IEC 17011 – General Requirements for Accreditation Bodies

ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories

ILAC –G20:2002 – Guidelines on Grading Non-Conformities

L-A-B Form 001 – Traceability Tracking

L-A-B Form 14 – Assessment Report

L-A-B Form 32 - Participants List

L-A-B Form 33 – Non-Compliance Report

L-A-B Form 205.1 – Technical Competency Evaluation

L-A-B Form 205.2 - Opening Meeting Minutes

L-A-B Form 205.5 – Assessment Matrix

L-A-B Form 218.5 – Accreditation Tracking – Calibration

L-A-B Form 218.6 – Accreditation Tracking - Testing

L-A-B Policy 009 - Accreditation of Multiple-Site Laboratories

L-A-B Policy 010 – Technical Competence Evaluation of Laboratories

6.14 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/24/09	Jason Stine	
Revision 1	10/05/10	Ryan Fischer	Removed "minor" as an identification of a noncompliance.
Revision 2	02/14/11	Randy Long	BMC to CMC change

7.0 Working with Laboratory Consultants

7.1 Purpose

This procedure defines the method for control of the assessment process when a Laboratory Consultant has been designated to operate on behalf of the laboratory during the assessment.

7.2 Responsibility

It is the responsibility of the Lead Assessor and the L-A-B Managing Director, having overall responsibility for the operations of L-A-B, are responsible for the conduct of assessment activities resulting in granting of L-A-B accreditation.

7.3 Introduction

L-A-B fully understands the necessity and role of a consultant engaged by the laboratory of L-A-B. Often the laboratory has need to obtain outside assistance in the development of such items including, but not limited to, quality system documentation, development and computation of best measurement of uncertainty, and proficiency testing programs.

L-A-B also understands that the assessment must be of the laboratory, its' facilities, and its personnel. In no circumstances, may the consultant or any person not considered key personnel of the laboratory speak on behalf of the laboratory during the assessment.

When the consultant has been given the authority to speak on behalf of the laboratory (generally during the standards' interpretation or document development phases) it must be clear to the laboratory that he/she must abide by the decisions being made on his/her behalf. The changes must become part of the laboratory's quality system.

If the consultant is responsible for portions of the quality system that no one else within the organization has those responsibilities, the consultant is considered key personnel (i.e. uncertainty of measurement, quality manager, proficiency testing or technical manager). If any of those are the sole responsibility of the consultant then the consultant needs to be present during the assessment. Additionally, if the consultant is key personnel then the requirements of ISO/IEC 17025 section 5.2 or appropriate L-A-B program requirement are to be enforced for the consultant. If the consultant is not considered key personnel then the laboratory is held accountable even though the consultant may still be assisting the laboratory.

7.4 Document Review Stage

It is permissible for the Lead Assessor to deal directly with the consultant provided the laboratory has given the authority to the consultant to act in his behalf.

It should always be made clear to the consultant and the laboratory that any decisions must be adhered to by the laboratory subsequent to granting of accreditation.

7.5 Pre-Assessment Visit

Normally during a pre-assessment visit, interpretation may be provided according to L-A-B guidance documents. The consultant will normally be an active party in this stage of the accreditation process.

The laboratory shall always participate in the pre-assessment activities. It is not acceptable for the consultant to act as the sole party representing the laboratory.

Whenever there is disagreement on interpretation or requirements in general, discussions must be between the Lead Assessor and the laboratory. The consultant may participate, but the final resolution (conclusion) must be between the Lead Assessor and the laboratory.

7.6 Opening Meeting and Assessment

While the consultant may attend this meeting, the laboratory shall be informed that the consultant may not be a participant and may only be a quiet observer.

All communication shall be between the assessment team members and the laboratory without interference from the consultant.

7.7 Closing Meeting

Recognizing that there may be need for the consultant to completely understand the deficiencies and corrective actions necessary to bring about conformance with the standard and the program requirements of L-A-B, there shall be no limitation on the consultant when speaking for the purpose of obtaining clarification. However, the consultant shall not be permitted to speak on behalf of the laboratory, thus leaving the laboratory out of the loop in the resolution process.

7.8 Summary

There is a place and need for consultants in the process of a laboratory achieving accreditation. Under no circumstances shall the consultant be the spokesperson for the laboratory during any of the active phases of the accreditation process; unless the consultant is considered key personnel.

The laboratory and its employees must speak on their own behalf and comply with their own quality system, processes and procedures.

A consultant shall not be asked to leave during any of the assessment stages unless the consultant is disobeying direct instructions of the Lead Assessor.

If at any time the consultant or laboratory insists on a process which violates any of the policies within this procedure, the Lead Assessor has every right to end the activity and refer the appeal to the Managing Director of L-A-B.

7.9 References

ISO/IEC 17011 – *General Requirements for Accreditation Bodies*

ISO/IEC 17025 – *General Requirements for the Competence of Testing and Calibration Laboratories*

7.10 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/24/09	Ryan Fischer	

8.0 Assessment Report Preparation and Submittal

8.1 Purpose

This procedure defines the requirements for preparation of the assessment documents by the Lead Assessor for presentation to the laboratory and L-A-B.

8.2 Responsibility

The Lead Assessor is responsible for compiling the necessary information and completing the required L-A-B documentation for submittal to the laboratory and L-A-B. It is the Lead Assessor's responsibility to assure all required assessment documentation is presented to the laboratory and submitted to L-A-B.

8.3 Assessment Documentation

8.3.1 Closing Meeting

The following assessment documentation is to be presented and left with the laboratory during the closing meeting:

8.3.1.1 Form 33 – Non-Compliance Report

Non-Compliances should be thoroughly reviewed and discussed with laboratory representatives. The Lead Assessor shall use the L-A-B Form 33 – Non-Compliance Report to formally issue the Non-Compliance to the laboratory. The Lead Assessor and laboratory representative must sign the last page.

The Form 33 provides details of the Non-Compliance and includes the following information:

a) *Unique N/C #*

Each Non-Compliance shall be given a unique identification;

b) *Requirement*

Each Non-Compliance must be cited against a specific element of ISO / IEC 17025, L-A-B Program Requirement or L-A-B Policy;

c) *Days to Complete*

The Lead Assessor will typically assign the laboratory 30 days for resolution of the Non-Compliance. The laboratory may formally request more time through L-A-B;

d) *Repeat N/C*

Identify if this is a repeat N/C from the last assessment;

e) *Serious N/C*

The Lead Assessor is responsible to determine the seriousness of the Non-Compliance utilizing the guidance given is section 6.9 of this handbook. Serious Non-Compliances shall be indicated on this form;

f) Assessor Approval Prior to Closure

The Lead Assessor is not responsible for approving the Non-Compliance. The Lead Assessor may request to be part of the Non-Compliance approval process by indicating on the form;

Note – L-A-B may request input from the Lead Assessor during technical review to assure appropriate closure of the N/C.

g) Description of Non-Compliance

The Lead Assessor must provide a detailed description of the situation resulting in the Non-Compliance. It is essential that specific details such as document numbers, certificate numbers, equipment ID, critical dates, identification of personnel, and all additional information surrounding the N/C are documented. L-A-B technical reviewers utilize this information to assure the laboratory takes the appropriate actions and provide sufficient supporting evidence for resolution of the N/C.

If necessary, L-A-B may require the Lead Assessor to provide additional detail supporting the Non-Compliance.

h) Acknowledgement of Understanding

The total number of Non-Compliances in this Form 33 for the specific location shall be indicated. The Lead Assessor and laboratory representative shall sign.

8.3.1.2 Form 33 - Multisite Assessments

For multisite assessments, a separate Form 33 should be completed for each site visited. For systematic Non-Compliances that occur at all locations the specific N/C should be cited at the main location and reference the additional locations observed.

8.3.1.3 The Scope of Accreditation

The Scope of Accreditation shall be approved by the Lead Assessor and signed by both the Lead Assessor and Laboratory Representative. Any changes to the Scope of Accreditation shall be clearly indicated on the scope itself. **A signed scope must be obtained every assessment**.

8.3.1.4 Form 14 – Assessment Report

The Form 14 – Assessment Report shall be completed by the Lead Assessor and reviewed with laboratory representatives during the Closing Meeting. This form must be signed by all assessment team members and a laboratory representative for each site visited.

The Form 14 summarizes the assessment activities and includes the following:

1) Multi-Site Locations

i. Total number of sites information can be found on the assessment plan;

ii. How many sites visited is intended to identify the total number of sites visited during this assessment project;

iii. Location of the technicians is to identify any technicians that are brought in from other locations to the site of the specific assessment for technical evaluation. Location and certificate number is to be identified for the location technicians witnessed;

2) *Change in Key Personnel*

Key Personnel will be identified on the assessment plan and should be utilized by the assessor to help estimate the appropriate time during the assessment for interviewing and/or technical witnessing. The area within the Form 14 is to be used to document any previously unidentified or changes to the Key Personnel found during the assessment;

3) *Do Onsite Man-Days Vary from Assessment Plan?*

If assessment requires more time to accomplish the assessment, the assessor will need to contact L-A-B prior to the additional time taking place and describe the circumstance within the assessment report. If time is being reduced it is not necessary for the assessor to contact L-A-B but a description as to why the assessment is being shortened is required;

4) *Review of Scope of Accreditation*

If the scope changes in any way or a parameter is to be removed it shall be defined within the Form 14 Assessment Report. Whether the situation be simply removing the item requested by the laboratory or that the laboratory can not technically support the parameter, shall be defined in the Form 14 Assessment Report;

5) *Summary of Non-Compliances*

The total number of non-compliances cited for this location is identified. Also indicated is the number of serious non-compliances, days for resolution and repeat findings. Non-Compliances shall be formally presented and detailed on the Form 33 – Non-Compliance Report.

6) *Assessor Recommendation*

The Lead Assessor recommendation should consider the adequacy of the organization, and procedures adopted by the laboratory to give confidence in the quality of its services and physical facilities (i.e. the environment and equipment, including calibration and maintenance) especially reviewing these with regard to the volume of work undertaken by the laboratory.

The Lead Assessor shall provide the following recommendations to L-A-B:

i. ***Unconditional Approval*** – The laboratory has met all accreditation requirements with no Non-Compliances and demonstrated technical competence of the scope;

ii. **Conditional Approval** – Accreditation recommended with conditions. Typically upon resolution of the Non-Compliances;

iii. **Suspension Recommended** - Examples may include: Complete breakdown of the quality system, lack of resources, and lack of technical competence covering the scope. Lead Assessors can recommend suspension. This recommendation should only occur with immediate discussions and input from L-A-B Managing Director or Program Managers;

iv. **On-Site Follow Up Visit Recommended** - Various situations may require a follow up visit to verify actions of the laboratory. Examples may include verification of effective implementation of serious Non-Compliances to assure technical

competence. If a laboratory has not demonstrated technical competence for a particular scope item, a follow up visit may be recommended. This recommendation must be discussed and approved by L-A-B prior to any arrangements being made;

v. **Desk Review Time Recommended** – This may typically occur for review of uncertainty budgets but other situations may warrant a desk review of documentation. This recommendation must be discussed and approved by L-A-B prior to any arrangements being made.

vi. **Initial Assessment Recommended to be Turned into a Preassessment** – The Lead Assessor may recommend, with the laboratories approval, to turn the Initial Assessment into a Preassessment. L-A-B shall be notified immediately of this recommendation and must approve this action.

7) *Site Assessment Summary*

The Lead Assessor shall utilize all of the information gathered during the assessment to provide a summary of the assessment activities. The summary statement provided on the Form 14 shall include comments on at least the following:

i. Competence of laboratory quality and technical staff;

ii. Conformity of the quality system;

iii. Observations and opportunities for improvement;

iv. General conclusion of the assessment activities.

8) *Closing*

Assure the following L-A-B assessment documentation has been reviewed, signed and provided to the laboratory:

i. Form 33 – Non-Compliance;

ii. Scope of Accreditation;

iii. Form 14 – Assessment Report.

If non-compliances are issued then the Lead Assessor must inform the laboratory of the L-A-B appeals process (SOP 203 – Appeals, Complaints, and Disputes).

9) *Estimate of Expenses*

All travel expenses for this project shall be indicated in the appropriate location. For multisite assessments the travel expenses may be completed on the final Form 14 at the closing meeting. Assessment Team Members expenses shall also be included. The Lead Assessor shall review and explain the estimate of expenses with the laboratory representative.

8.3.1.5 Assessment Document Submission to L-A-B

The Lead Assessor shall submit to L-A-B the appropriate assessment documentation listed on the appropriate L-A-B Assessor Documentation Checklist (Form 205, Form 403.1) upon completion of the assessment.

a) L-A-B Form 14 – Assessment Report – Must be submitted to L-A-B immediately after the closing of the assessment. This may be faxed or e-mailed to L-A-B;

b) The Lead Assessor shall submit the completed Assessor Documentation Checklist and all required documentation found on this form to L-A-B within **7 days** after the completion of the assessment;

c) Documents must be submitted L-A-B electronically;

8.3.1.6 Do Not Send the Following

a) If an affiliate performs an ISO 9000 or similar audit, Do not send any of the supporting documentation from those organizations;

b) Any Affiliate's forms in support of ISO 9000 or similar audit;

c) The quality manual of the laboratory;

d) Unidentified exhibits.

8.4 Requirements

8.4.1 Assessment Documentation Requirements

a) Assessors and Technical Experts must submit all assessment documentation within seven days of the closing of the assessment. For multi site assessments the assessment package must be received within seven days of the closing of the final sites assessment.

b) Upon receipt of the assessment package, L-A-B will review the submittal of documents to assure that all of the required assessment documentation has been received. The assessment package will not be considered complete until all of the required documentation is received by L-A-B.

c) L-A-B will notify Assessors and Technical Experts of incomplete assessment packages and any required documentation.

d) L-A-B will not issue payment to the Assessor or the Technical Expert for the assessment activities performed until all required documentation has been received and approved by L-A-B.

8.5 References

ISO/IEC 17011 – General Requirements for Accreditation Bodies

ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories

L-A-B Policy 008 – Assessor Contracts and Requirements
L-A-B Form 14 – Assessment Report
L-A-B Form 33 – Non-Compliance Report
L-A-B Form 205 – Assessor Documentation Checklist
L-A-B Form 403.1 – DoD Assessor Documentation Checklist

8.6 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/24/09	Jason Stine	

9.0 Assessor Assignment, Scheduling, Expenses, and Payment

9.1 Purpose

To establish L-A-B procedures regarding assessment assignment, scheduling, fair and consistent practices for the charging of time and expenses, and payment to independent contractor Assessors and Technical Experts for conducting and completing L-A-B assessment activities.

9.2 Responsibility

L-A-B Managing Director and Accounting have complete responsibility to establish rules and criteria for the time and expenses charged directly or indirectly to the clients of L-A-B.

9.3 Assessor Assignment

L-A-B Assessors and Technical Experts are either L-A-B employees or subcontracted independent contractors. L-A-B utilizes only qualified Assessors and Technical Experts who are expected to function in a professional manner at all times when working on an L-A-B assessment.

At the start of each assessment L-A-B will assign appropriate qualified personnel a specific role for that assessment. Each L-A-B Assessor or Technical Expert has been qualified by L-A-B for a specific qualification level such as Lead Assessor, Team Assessor, Technical Expert, or as defined by L-A-B. When conducting an assessment, the Assessor or Technical Expert is paid at a level consistent with his / her role in the assessment process.

An example is a qualified Lead Assessor **A,** working on an assessment team as an assessment team member with another qualified Lead Assessor **B**, working as the Lead Assessor for this assignment. In this example, Assessor **A** would be paid at the rate of a Team Assessor and Assessor **B** at the rate of a Lead Assessor.

The L-A-B payment schedule can be changed at any time by L-A-B, and when changed will have an "effective date" beyond which the new rates and/or procedures will apply to all assessment activities that occur after the "effective date".

9.4 Assessment Scheduling

Assessors and Technical Experts are typically scheduled by L-A-B to conduct an assessment several months in advance of the date by which the assessment must be completed. It is the responsibility of L-A-B to assure that the scheduled assessment utilizes a qualified and suitably available Assessor or Technical Expert. Qualifications for each L-A-B Assessor and Technical Expert are established and maintained by L-A-B.

A "scheduled" assessment is not considered an "assignment" until a firm assessment date has been agreed upon between the client, L-A-B, and the Assessor or Technical Expert. Once dates have been agreed upon the assessor must complete an assessment plan for final L-A-B and client approval prior to making travel arrangements. Once approved, L-A-B will notify the assessor so that the appropriate travel arrangements can be made. Any travel arrangements made prior to L-A-B approval are not subject to reimbursement. L-A-B can, at its sole discretion, change a scheduled assessor at any time.

9.5 Administrative Process

L-A-B Operations will typically notify Assessors or Technical Experts by e-mail of an upcoming assignment. The Assessor or Technical Expert will initially receive a summary of the relevant assessment information from L-A-B. The Assessor or Technical Expert must confirm his / her willingness and qualifications to conduct such an assessment and return all required paperwork to L-A-B, if not already on file.

L-A-B Operations will notify the assigned Assessor or Technical Expert of the specific timeframe for which the assessment must take place. The Lead Assessor must promptly notify L-A-B Operations of a suggested assessment date. Suggested assessment dates must be proposed as soon as possible, and fall within 30 days before or after the SBD date given by L-A-B Operations. If a Technical Expert is utilized the Lead Assessor and Technical Expert must agree on a suggested assessment date(s). Until the laboratory notifies L-A-B Operations in writing (e-mail is acceptable), the assessment date is not confirmed.

If the laboratory does not adhere to the requirements of L-A-B Policy 004, the assessment may be rescheduled at the risk of suspension of the laboratory. If rescheduling is necessary the suggested assessment date process is performed again.

9.6 Assessment Completion

Upon completion of the assigned assessment, the Lead Assessor must complete and FAX or e-mail a signed copy of L-A-B Form 14 – Assessment Report to L-A-B Operations before leaving the client's site. This is confirmation for L-A-B that the scheduled assessment has taken place and provides immediate details to L-A-B staff of the assessment outcome. For multisite assessments, a separate Form 14 must be completed for each site visited.

Within 5 working days of the completion of an assessment event, each L-A-B Assessor or Technical Expert must complete a Form 16 L-A-B - Expense Report and e-mail it to accounting@l-a-b.com. Once a Form 14 – Assessment Report and a completed L-A-B Form 16 - Expense Report form are received and approved by L-A-B Accounting the payable is recorded. The client is then invoiced using these documents as indicators of work and travel expended.

L-A-B Accounting will use the current manday rate as a basis for paying assessors appropriate with their assigned activity. The L-A-B Managing Director must approve all variations from the scheduled mandays expended for activities occurring during assessment activities.

An Assessor or Technical Expert will not be paid until all L-A-B required documentation is correctly completed and accepted by the appropriate L-A-B staff. This excludes post-assessment Corrective Action Review.

9.7 Expenditures

9.7.1 Procedure

Assessors and Technical Experts of L-A-B are contracted employees and are expected to function in a professional manner at all times while representing L-A-B. It is expected that they take into consideration the total cost to the client when making their decisions regarding travel means and their associated time.

L-A-B prides itself in the efforts made by its assessors in containing costs to the client, and also recognizes its obligation to treat assessors in a fair and professional manner.

L-A-B does not inflate the travel / living expenses for charges to the client and utilizes the daily manday rate for additional hours charged by the assessor(s) for the assessment visit, document review, and report preparation, where applicable.

Expenses for time, travel, and living that occur during assessment activities may be reimbursable to the contracted Assessor or Technical Expert.

9.7.2 Expenses

Travel time and expenses are expected to be kept to a minimum and every effort shall be made to take advantage of the lowest cost airfares, hotels, automobile rentals, and keep personal automobile mileage low. The following conditions shall apply:

a) Personal automobile mileage should be kept to a minimum. Mileage incurred while performing assessment related activities may be billed at the current accepted IRS mileage rates for business travel.

b) Flights are acceptable if it is more appropriate for the Assessor or Technical Expert to fly because the airfare is approximately the same or less than the mileage charges to be derived from the calculation of miles driven and the accepted IRS mileage rates for business travel.

c) Airline arrangements shall be made as far in advance as possible to take advantage of reduced fares. Care should be taken to avoid multiple connections which may reduce air fare, but significantly increase travel time. A proper balance is expected to be achieved.

d) Non-refundable / non-changeable airline tickets are preferred for cost savings.

e) Auto rentals shall be for the lowest cost car available which will also provide a safe means of travel for the Assessor or Technical Expert.

f) Hotel arrangements shall be made as far in advance as possible to take advantage of reduced rates. It is expected that the lowest cost hotel, which provides a proper level of safety for the Assessor or Technical Expert will be utilized.

g) When conducting business for a client, it is appropriate to request that the client suggest, and perhaps even reserve the hotel room for the Assessor or Technical Expert. It is the client who will be receiving the bill for the hotel from L-A-B and should therefore have the opportunity to suggest the selection. The Assessor or Technical Expert may reject such a selection if it is questionable for the safety of the L-A-B personnel.

h) L-A-B related activities of the Assessor or Technical Expert, which is just prior to or immediately after the visit on behalf of L-A-B, may share expenses among all of the related laboratories for the duration of the trip.

i) Assessor sponsored meals are not permitted except when authorized by the L-A-B Managing Director prior to the trip.

9.7.3 Travel Time

Assessors and Technical Experts may be eligible for up to $160 reimbursement of their travel time for assessment related travel. The Assessor or Technical Expert is eligible for payment for normal travel toward their destination. Travel payment is based on normal driving and/or flight time. Airport layover time and delays or driving delays due to traffic or weather are not eligible for payment. The following formula will apply for calculation of travel time payment up to $160:

(Total Normal Travel Time – 3 Hours) ($40) = Travel Payment

9.7.4 Additional Time / Cost Approval

All requests for additional payment for travel time beyond what is stated above requires written approval of the L-A-B Managing Director.

Receipts and any other documentation necessary to substantiate the hours to be paid shall accompany the expense report submitted. This will be made available to the client upon request after they receive the invoice for the assessor's travel expenses, time and other living expenses.

Assessors and Technical Expert are required to record the total travel time expenses on the L-A-B Form 14 – Assessment Report.

If airfare is to be more than $800 the Assessor or Technical Expert shall obtain prior approval from L-A-B. This is to be done using L-A-B Form 14.1. The signed form is to be sent to L-A-B Operations by e-mail (operations@l-a-b.com) or fax at (260) 637-2791. L-A-B Operations will then provide additional instructions to the Assessor or Technical Expert as needed.

9.7.5 Expense Report and Receipts

Assessors and Technical Experts are required to send a completed L-A-B Form 16 - Expense Report to L-A-B Accounting within five working days of completing the activity for which the expense is applicable.

Legible receipts for expenses of $25 and over shall be sent to L-A-B Accounting. The expense report and receipts are preferred by e-mail but may be faxed or mailed to the following address.

Laboratory Accreditation Bureau Accounting
11617 Coldwater Road Ste 101
Fort Wayne, IN 46845
E-mail accounting@l-a-b.com
Fax (260) 637-2791
Phone (260) 637-2705

These receipts must be received before payment of the assessment activity can occur. If the client requests a more detailed listing of expenses after receiving the L-A-B invoice, accounting may request additional information to support expenses. Additional requests may be referred directly to the Assessor(s) or Technical Expert(s) so that such dealings may continue to be directly between the Assessor(s) and the client.

9.8 Assessor Payment

The Lead Assessor is required to submit all assessment documentation listed on the appropriate Assessor Documentation Checklist in accordance with Section 8.0 of this handbook. Technical experts are also required to submit all agreed upon documentation.

Assessors and Technical Experts will normally be paid in 30 days from the receipt of the L-A-B Form 16 - Expense Report and a valid and acceptable invoice. If L-A-B delays payments for reasons other than for incomplete and unapproved submissions from the Assessor or Technical Expert then L-A-B will pay 1.5% per month (prorated daily), as a Finance Fee, to the Assessor or Technical Expert for each day beyond the 30 days mentioned above.

L-A-B will not accept "piecemeal" invoices for work done before an assessment takes place. All work for an assessment, including any preparation or document review or compilation charges or other expenses, must be invoiced at the same time after the completion of an on-site assessment event.

Post-assessment corrective action resolution fees and expenses must be submitted separately. Any post-on-site-assessment CAR efforts or expenses must be pre-approved and requested by L-A-B Managing Director. It is expected that L-A-B staff assessors will complete the majority of post-assessment CAR work.

L-A-B will issue payment to the Assessor or Technical Expert by either direct deposit or check. A W-9 must be completed and on file for each person prior to issuing payment. If direct deposit is preferred a deposit authorization form must be completed.

9.9 Satisfactory Performance

L-A-B has scheduled and assigned an assessment to a particular qualified Assessor(s) or Technical Expert(s) with the expectation that the Assessor or Technical Expert will complete the job in accordance with L-A-B Policies and Procedures and perform in a fully satisfactory and timely manner. Any material deficiencies in performance or delays by the Assessor, which adversely affect the professional, technical or business reputation of L-A-B, or prevent L-A-B from invoicing and collecting fees from the client assessed, can represent "non-completion of the job assignment", and a basis for non or partial payment to the Assessor or Technical Expert involved.

If an Assessor or Technical Expert disputes the "non-completion of the job assignment" by L-A-B, he/she may appeal to the L-A-B TAG. Any appeals, complaints or disputes will be handled in accordance with L-A-B SOP 203 under the full responsibility of the L-A-B Managing Director.

9.10 Contacts and Reporting

All Assessors or Technical Experts report to the L-A-B Managing Director. Contact and issues relative to the conducting of assessments should go through the appropriate L-A-B program Manager or the Managing Director.

9.11 References

L-A-B Policy 004 – Delays Caused by Laboratory
L-A-B Form 14 – Assessment Report
L-A-B Form 14.1 – Additional Time / Cost Approval
L-A-B Form 16 – Expense Report

9.12 Revision History

Revision Level	Revision Date	Revised By	Description
Original	05/01/09	R Douglas Leonard	Initial Release

1.0 Purpose

This Annex defines the criteria used to prepare for and assess the laboratories uncertainty of measurement. This Annex applies to the Lead Assessor and members of the Assessment Team.

2.0 Responsibility

The Lead Assessor and members of the Assessment Team are responsible for ensuring that all functions of this Annex are fulfilled.

3.0 Recommended Practice for Assessing a Laboratory's Uncertainty Budget

"The calculation of uncertainty for a measurement is an effort to set a reasonable bounds for the measurement result according to standardized rules."

– Ted Dorion and John Stoup (NIST)

ISO/IEC 17025 and L-A-B Policy 001 set the rules for L-A-B applicant and accredited laboratories related to measurement uncertainty and calibration and measurement capability. It is up to the assessors, staff and TAG members to assure the rules are followed by the laboratories by fully understanding ISO/IEC 17025, Policy 001, the calibration and/or test being assessed and all related documents.

4.0 Recommended practice for reviewing the Calibration and Measurement Capability (CMC):

4.1 First, find out if the client is reporting the CMC on the Calibration Certificates they provide their clients. If they are make sure the CMC was computed with their worst capability at the highest extent of the range.

4.1.1 Environmental conditions should be at the taken into account at the fullest swing in the laboratory.

4.1.2 If they are doing on-site work they must have considered that work in the budget.

4.2 They should consider the worst resolution for the unit under test (UUT) in the budget.

4.3 Next, look at the Range of the Budget(s)

4.3.1 Make sure they have appropriate budgets covering the range they have on the scope.

4.3.2 If the scope has a formula such as $(10 + 2L)$ µin there should be a minimum of two budgets. One should be at the lower end of the range and the other should be at the high end. The best method in developing this range of uncertainty would be to have a third budget in the middle of the range to assure a consistent representation of uncertainty throughout the range.

4.4 Next, look at the sources of uncertainty in the budget

4.5 Uncertainty sources come in two major classifications.

4.5.1 Type A: Uncertainty is evaluated statistically. They come from repetitive measurements to derive one standard deviation. Typically in the case of CMC

they are done on the ideal, but in the case of #1 above interview to assure a less than ideal UUT was used.

4.5.2 Type B: Uncertainty is everything else not based on repetitive measurements. These types of uncertainty typically are from:

4.5.2.1 UUT resolution.

4.5.2.2 Environment of the calibration or test including the specification of the instrument measuring the environment and its inherent uncertainty and the effect on the UUT and the measuring device.

4.5.2.3 Deformation if contact is being made on something during the measurement.

4.5.2.4 Reference standards / artifacts / equipment specifications... not forgetting if you are taking actuals from the calibration certificate then drift of that calibration should be taken into account.

4.5.2.5 Inherent uncertainty from its calibration.

4.6 After assuring that the appropriate sources of uncertainty are on the budget you can move to looking at the "stated uncertainty limits" for that source. This is the number prior to being divided by the distribution. They need to all be in the same units so that the calculation can work. At times some laboratories fail to translate the environmental conditions to the SI unit related to the end result. Additionally if the laboratory wants to discount some of the sources because the stated limits are negligible related to the end result they may do so but must prove why they did it. Sample the "stated limits" back to their origin. It is problematic if the budget is dated two or three years ago and they are having their reference standards/artifacts and equipment calibrated every year. The inherent uncertainty for the artifact may have changed.

4.7 With the "stated uncertainty limits" sampled next look at the chosen distribution to divide that number.

4.8 For type A repeatability the goal is to one standard deviation for computed uncertainty at the far right hand column. Many laboratories make the mistake of further dividing their standard deviation by 2 by picking a normal distribution;

4.9 For type B specifications, resolution, and temperature controlled with a specification the divisor is typically a rectangular (1.732);

4.10 For inherent uncertainty it can be argued it is a type A or type B taken from the calibration certificate based on statistics of the prior lab or not. Either way the divisor is typically normal (2) unless it was divided by 2 in the far left "stated uncertainty limits", then it is a 1.

4.11 Now that they have the computed uncertainty (all the sources now as one standard deviation) look at each line item and see which one(s) are the highest contributors. Again look at the "stated uncertainty limits" for those contributors. Make sure they are accurate.

4.12 Finally assure the final number is computed utilizing the root-sum-square method and multiplied by 2 to provide approximately 95% confidence level in the calculation.

4.13 Most importantly confirm the final number is appropriate taking into consideration other CMC's reported for similar methods of test or calibrations. To find out Calibration and Measurement Capabilities of National Metrology Institutes follow this link: http://kcdb.bipm.org/appendixC/default.asp

5.0 Recommended practice for reviewing real time uncertainty analysis

5.1 When the laboratory is computing real time uncertainty further defining the real uncertainty for a measurement the practice of reviewing the budget is almost the same as given for the CMC with a few exceptions:

5.1.1 Repeatability should be estimated for the actual measurement taking place real time on the UUT including degrees of freedom.

5.1.2 The environmental conditions may be further defined to actuals but must represent the conditions during the entire calibration or test. Not just the beginning or the end.

5.1.3 The actual resolution of the UUT should be taken into account. Not the ideal.

5.1.4 The actual uncertainty on the calibration certificate or test report shall never be lower than the CMC on the scope.

5.2 It is recommended that the assessor make notes concerning the laboratories budgets directly on the budget they turn into L-A-B with the technical package. This will allow L-A-B staff and the TAG technical reviewer to understand the methodology of the assessor and the client as it relates to each reviewed budget. Remember the goal is to have the laboratory provide the most appropriate estimate for their measurements.

6.0 References

ISO/IEC 17025 – *General Requirements for the Competence of Testing and Calibration Laboratories*

Ted Dorion and John Stoup (NIST)

BIPM – Key Comparison Database

7.0 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/20/06	R Douglas Leonard	
Revision 1	07/24/09	Jason Stine	Updated formatting to align with the Assessor Handbook
Revision 2	02/14/11	Randy Long	BMC to CMC change

1.0 Purpose

The following is a collection of helpful assessment techniques gleaned from L-A-B's experience in assessing laboratories.

2.0 Responsibility

It is the responsibility of the qualified Assessor to apply the proper techniques when performing an assessment and for the L-A-B Technical Staff to monitor the feedback from the laboratories about the assessment and Assessor.

3.0 Set the tone for the assessment

3.1. Look the part: dress appropriately.

3.2. Act the part: be businesslike, maintain a low profile.

4.0 Understand your effect

4.1. You represent L-A-B.

4.2. Your findings may have positive and/or negative effects on laboratory staff members.

4.3. Your conclusions may change (enhance or limit) the laboratory's ability to do business.

5.0 Start off on the right foot

5.1. Give the staff time to adjust to your presence.

5.2. Give management a chance to demonstrate their support.

6.0 Proper planning of the assessment and keeping on track

6.1. Avoid wasting time.

6.2. Conform to the laboratory's regular operating schedule as much as possible.

6.3. Don't allow socializing to dominate the schedule.

6.4. Don't keep going over the same ground.

6.5. Ask who, what, when, where, how, and why questions that elicit substantive answers.

6.6. Ask hypothetical questions (refer to Annex C – Interview Techniques).

6.7. For clarity, verbalize your understanding of specific procedures and how the laboratory operates.

6.8. Return to an area, if necessary, to gain new information or understanding.

6.9. Discuss and clarify non-conformances right away.

6.10. Try to answer all questions but call L-A-B (or follow up) if you cannot respond knowledgeably.

6.11. Don't emphasize areas in which you have a particular interest at the expense of the assessment.

6.12. Be determined, decisive and direct.

6.13. Be honest and fair.

6.14. Be independent; maintain your objectivity.

6.15. Don't be confrontational; avoid conflict.

6.16. Don't argue; if the staff is disdainful, maintain your professionalism and be firm.

6.17. Keep a sense of proportion; don't pursue trivial matters.

6.18. Be constructive and helpful.

6.19. Don't conduct the assessment as if it were a form of punishment.

6.20. Be alert to conflicting information from different sources.

6.21. Don't allow the staff to bog you down with detail.

6.22. Recognize a "cover-up"; don't allow the staff to emphasize the strong points and gloss over the weak points.

6.23. Don't get involved in areas that are not within the requested scope of accreditation.

6.24. Avoid comments about specific manufacturers, suppliers, equipment, or products.

6.25. Avoid comments about other laboratories or individuals outside or within the laboratory.

6.26. Avoid involvement in intralaboratory problems, conflicts, or policies.

6.27. Avoid becoming an advocate or lobbyist for anyone in the laboratory.

6.28. Don't agree to provide separate "unofficial" findings to the laboratory.

6.29. Avoid all situations which might be considered as undue or improper influences on your findings.

6.30. Be calm and courteous; thank the staff for its time, assistance and hospitality (even if the visit was strained).

7.0 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/24/09	Jason Stine	Initial Release

1.0 Purpose

This document defines some techniques that should be utilized when performing an assessment as a qualified Assessor of L-A-B.

2.0 Responsibility

It is the responsibility of the qualified assessor to apply the proper techniques when performing an assessment and for the L-A-B Technical Staff to monitor the feedback from the laboratories about the assessment and Assessor.

3.0 Effective Communication

- Effective communication is key to a good interview

1. I know you believe you understand what you think I said, but I am not sure you realize that what you heard is not what I meant. Simply put, what is said may be significantly different from what is heard or intended.

- The three logical steps to communicating are

1. what is said;
2. what is heard;
3. what is understood.

- Failures occur when there is a breakdown between any two of these steps as follows

1. "What is said may not be what is heard." This may be caused by such things as lack of interest, boredom, diverted attention, or noise.
2. "What is heard may not be understood." Causes for this may be language problems, unclear messages, use of technical jargon, or speaking above the listener's qualification level.
3. "What is understood may not be accepted." This is bias; the listener may have a negative attitude toward the subject or the speaker.

- There are some nonverbal factors to be considered as well

1. Body posture;
2. facial expressions;
3. Even general appearances have to do with looking and acting the part of a professional Assessor. Be aware of the image you are projecting, it may have a direct bearing on the effectiveness of the interview. Other considerations such as vocal tones, volume and delivery can have a direct effect on how the listener receives the communication. Even bad news can be softened if said properly.
4. This brings us to a discussion of effective questioning techniques. If we assume as the Assessor, you have done your homework, and know what questions to ask to gather the data needed, then your job becomes that of a good listener. There is an old rule that says effective interviewing is 20% asking and 80% listening. This implies that the interviews must be well-planned, not only as to subject matter, but also the types of questions asked in order to elicit the desired responses.

- 5 basic types of questions

1. **Open** - These questions cannot be answered by a simple yes or no and usually require an explanation of some sort. They provide interviewees an opportunity to discuss, in some detail, areas they are familiar with, thus making them more comfortable with the process. Open questions also allow you, as the interviewer, to put to good use your listening skills.

   Example - "Please explain your process for cleaning gage blocks prior to calibration."

2. **Closed** - This type of question typically requires only a yes or no response. Although closed questions have their place, little information is gained from the response and they tend to restrict communication. Too many closed questions can cause the interview to seem more like an interrogation and less like an interview

   Example - "Do you clean gage blocks prior to calibration?"

3. **Clarifying** - Clarifying questions are intended to assure that what was said is what was heard and understood. They are used to obtain details, enhance understanding and eliminate ambiguity.

   Example - "You've explained how you clean gage blocks. Could you tell me more about the chemicals you use?"

4. **Leading** - These are biasing by nature. They tend to suggest an expected answer, and should be carefully avoided.

   Example - "You do allow 24 hours of stabilization time, don't you?"

5. **Antagonistic** - Antagonistic questions are another form of interrogation. They arouse negative emotions and tend to put people on the defensive.

   Example - "Why is it that 40% of your gage blocks fail a flatness test because they were improperly cleaned?

4.0 Other Forms of Communication

1. **Silence -** Another useful weapon in the battle to obtain necessary information is silence. Remaining silent after a response to a question implies that more information is wanted and that the answer provided is not sufficient, while not embarrassing interviewees by telling them so. (This assumes, of course, there is more information to be had.) Silence has been described as a vacuum begging to be filled with talk. It may be discomforting to the interviewee but, if well placed, can be effective in extracting information.

2. **One on One -** Interviews are usually more effective when conducted one-on-one. People are more likely to "open up" if their coworkers (or bosses) are not listening. However, there may be some applications for interviewing more than one person at a time. An example may be interviewing all operators of a measurement system that takes more than one to operate.

3. **Listen** - Now that we've gotten the interviewee to talk, it is the Assessor's turn to listen. Remember the 80%/20% rule and recognize that if you're talking, you're not learning. The whole point of the interview is to gather pertinent data about the system or process being assessed. A good listener will let the speaker know that he or she is listening without interrupting. This may be done by a strategically placed head nod or even simple eye contact. Again, your image is important. If interviewees get the feeling you're not really listening, they will likely stop talking. Take appropriate notes. Record the key points during the interview and fill in the details as soon as practical afterwards. Constant writing of notes during the interview can be alarming to the interviewee. Using your interview planning notes is an effective way to do this. When planning questions we at least expect the answers to fall within a certain range. The expected possible responses can be recorded as a minichecklist and checked off during the interview. It is bad form, however, to anticipate answers and interrupt speakers before they are finished. Pay close attention to what is being said, and ask clarifying questions to be sure you understand the response.

4. **Manners** - Always be courteous and professional in your actions. If an interviewee is uncooperative, try to work around it by altering your interview technique. However, if you cannot obtain the information you need for a proper assessment, let the lead Assessor and/or the appropriate laboratory manager know of the problem. The laboratory is responsible for making objective evidence available to the Assessors. Thank interviewees for their time and effort, regardless of their attitude, and keep the door open for follow-up questions as need arises.

5.0 Revision History

Revision Level	Revision Date	Revised By	Description
Original	07/24/09	Jason Stine	Initial Release